

of its PSD permit, including, if necessary, retrofitting with BACT;

(iii) If Cabras Unit No. 4 operates either prior to the issuance of a final PSD permit or without BACT equipment, Cabras Unit No. 4 shall be deemed in violation of this waiver and the CAA beginning on the date of commencement of construction of the unit.

(2) A waiver of the requirement to obtain a PSD permit prior to the operation of the unit identified in the 1995 Petition as Cabras Unit No. 3 is granted subject to the following conditions:

(i) The protocol to be followed for the ICS of fuel switching for electric generating units shall be modified to require the use of fuel oil with a sulfur content of 2.00 percent or less during offshore wind conditions. This fuel shall be fired in Cabras Power Plant Units Nos. 1 through 3 and in Piti Power Plant Units Nos. 4 and 5.

(ii) Cabras Unit No. 3 shall operate in compliance with all applicable requirements in its permits to construct and to operate as issued by Guam Environmental Protection Agency.

(iii) The waiver provisions allowing Cabras Unit No. 3 to operate prior to issuance of a PSD permit shall expire on August 15, 1996, or upon the receipt by GPA of a PSD permit for Cabras Unit No. 3, whichever event occurs first.

(3) On or before October 15, 1995, GPA shall submit to EPA, Region IX, a report concerning the operation of Cabras Unit No. 3 and the construction of Cabras Unit No. 4. The report shall contain:

(i) A summary of GPA's conclusions from its wind tunnel study;

(ii) A description of the alternatives available to assure compliance with all air quality requirements, including PSD requirements, during the operation of Cabras Units Nos. 3 and 4;

(iii) A description of the alternative GPA chooses to assure compliance with all air quality requirements, including PSD requirements, during the operation of Cabras Units Nos. 3 and 4; and

(iv) A plan of implementation by GPA.

[FR Doc. 95-23107 Filed 9-15-95; 8:45 am]

BILLING CODE 6560-50-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

#### 42 CFR Part 405

[BPD-766-F]

RIN 0938-AG21

#### Medicare Program; Standards for Quality of Water Used in Dialysis and Revised Guidelines on Reuse of Hemodialysis Filters for End-Stage Renal Disease (ESRD) Patients

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule.

**SUMMARY:** This final rule revises the Medicare conditions for coverage of suppliers of end-stage renal disease services. The revisions remove general language in the regulations regarding water quality; incorporate by reference standards for monitoring the quality of water used in dialysis as published by the Association for the Advancement of Medical Instrumentation (AAMI) in its document, "Hemodialysis Systems" (second edition); and update existing regulations to incorporate by reference the second edition of AAMI's voluntary guidelines on "Reuse of Hemodialyzers."

**EFFECTIVE DATE:** These regulations are effective on October 18, 1995. The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of October 18, 1995.

**FOR FURTHER INFORMATION CONTACT:** Jackie Sheridan, (410) 966-4635.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Section 1881 of the Social Security Act (the Act) authorizes Medicare coverage and payment for the treatment of end-stage renal disease (ESRD) in approved facilities that provide dialysis to ESRD patients. The Health Care Financing Administration (HCFA) grants approval of ESRD facilities after they have been surveyed by a State agency. The State survey agency determines the facility's compliance with the conditions specified in regulations at 42 CFR part 405, subpart U. Medicare payment is limited to ESRD services furnished by facilities meeting these conditions.

##### A. Water Quality

The existing regulation governing the quality of water used in dialysis (§ 405.2140(a)(5)) requires that the water be analyzed periodically and treated as

necessary to maintain a continuous supply that is biologically and chemically compatible with acceptable dialysis techniques. The lack of specificity of these requirements makes it difficult for State agency surveyors to measure facility compliance with the standard.

Realizing that water quality is one of the most important aspects of health and safety in dialysis led us to consult with the Public Health Service and various other professionals in the dialysis industry to redefine the standards used by State surveyors in determining compliance with the regulations. As a result of these consultations, we concluded that there was a need to establish specific measurable standards regarding the quality of water used in dialysis. According to the Public Health Service's Center for Disease Control and Prevention, the Association for the Advancement of Medical Instrumentation (AAMI) standard on water quality is the only standard available, is accepted by the medical community and is currently used by most facilities.

The 1992 AAMI standard, "Hemodialysis Systems," reflects the collective expertise of a committee of health care professionals, in conjunction with device manufacturers and government representatives. This committee developed a standard of performance for manufacturers that will, at a minimum, promote the effective, safe performance of hemodialysis systems, devices, and related materials. The standard includes specific water quality requirements and has an appendix that provides a guideline for the device user with specific emphasis on water purity assurance and monitoring. This standard is outcome-oriented in that it stipulates only specific biological and chemical water purity levels and does not restrict the methods used by facilities to attain and maintain the acceptable levels.

Each AAMI standard or recommended practice is reviewed at least every 5 years because of constant changes in medical technology and to clarify or improve existing guidelines. The standard was originally published in 1982. In 1986, the AAMI Renal Disease and Detoxification Committee appointed task groups to carefully review specific areas of the standard. After review by the task groups and the full committee, a proposed revision was drafted. This document, "Hemodialysis Systems" (second edition), was voted on by the committee, reviewed by the public, and was approved on March 16, 1992.

### *B. Reuse of Hemodialyzers*

Section 1881(f)(7) of the Act requires the Secretary to establish protocols for reuse of hemodialyzers for those facilities that voluntarily elect to reuse the filters. Reuse can be accomplished through a variety of techniques that involve the cleaning, disinfecting, and preparing of disposable hemodialysis devices for subsequent use by the same patient. Although the potential exists for adverse patient outcomes from reuse, reprocessing and reuse of dialyzers are safe when done properly.

Existing regulations at § 405.2150 require ESRD facilities reusing hemodialyzers to meet the voluntary guidelines and standards adopted by AAMI and issued in July 1986 as "Reuse of Hemodialyzers." The AAMI guidelines on reuse of hemodialyzers are based on the national consensus of physicians, other health care professionals, government representatives, patients, and industry. These guidelines (directed to health professionals) describe the details of reprocessing dialyzers and address various areas such as personnel qualifications and training, patient considerations, equipment, reprocessing supplies, monitoring during dialysis, quality assurance and quality control.

After review by the AAMI Renal Disease and Detoxification Committee and the public, the second edition of the "Reuse of Hemodialyzers" was approved. The second edition is directed to the physician in charge of hemodialyzer reprocessing (using a manual or automated method) and describes the essential elements of good practices for reprocessing dialyzers to help assure safety and effectiveness.

## **II. Provisions of the Proposed Regulations**

We published in the **Federal Register** (59 FR 6937) on February 14, 1994, a proposed rule to amend the Medicare regulations to incorporate by reference the AAMI standard for water quality and the AAMI guidelines for monitoring purity of water for hemodialysis found in the following sections of "Hemodialysis Systems" (second edition):

- 3.2.1—Water Bacteriology
- 3.2.2—Maximum Level of Chemical Contaminants
- Appendix B, section B1 through B5—Guidelines for Monitoring Purity of Water Used for Hemodialysis.

We proposed that this incorporation by reference would replace the existing general language in § 405.2140(a)(5) which requires that water used for dialysis must be analyzed periodically

and treated as necessary to maintain a continuous supply that is biologically and chemically compatible with acceptable dialysis techniques.

The February 14, 1994, proposed rule also specified the proposed incorporation by reference of the 1993 (second) edition of the AAMI guidelines on "Reuse of Hemodialyzers" to replace the previously incorporated 1986 edition. In addition, we proposed to amend § 405.2150 to remove paragraph (a)(2) concerning staff exposure to chemical germicides, paragraph (a)(3)(iii) concerning reporting adverse patient reactions to the manufacturer, and paragraph (b) concerning the standard for dialyzer caps. These topics (included in the three paragraphs previously mentioned) are covered in the following sections of the revised 1993 AAMI guidelines that are now being incorporated by reference:

- Section 8—Physical plant and environmental safety considerations
- Section 11—Reprocessing
- Section 13—Monitoring
- Annex A—Section A11.4—Germicide.

The proposed rule specified that copies of both AAMI publications may be purchased from AAMI and are available for inspection at the HCFA Information Resource Center or the Office of the Federal Register.

## **III. Analysis of and Responses to Public Comments**

We received five timely public comments on the February 1994 proposed rule. All commenters were generally supportive of the proposed revisions. Their comments and our responses are discussed below.

### *A. General*

*Comment:* One commenter noted that the Government's regulatory process is slower than the private sector's in making changes. They recommended that we develop a mechanism to automatically incorporate the most recent revision of AAMI guidelines into the regulation rather than revise the regulations each time the AAMI guideline is updated.

*Response:* We acknowledge that the process of issuing a revision to the regulations each time the AAMI guidelines are updated results in delay in giving the updated guidelines the force of law. It certainly would be simpler for us to merely adopt the most recent version of the AAMI guidelines automatically upon update as the commenter suggested. However, we have some concerns that such a system may not be consistent with our

obligation to the ESRD facilities that would be affected.

Under the current system, we carefully review and consider the changes made in the AAMI updates and make a determination as to whether it is appropriate and necessary to incorporate the AAMI provisions in our regulations. Then we offer the public an opportunity to participate in the regulation process through a comment period.

If we were to adopt the commenter's suggestion, the industry would be required to comply with the AAMI guidelines regardless of whether changes are beneficial to Medicare beneficiaries or unduly burdensome to facilities.

In this regard, we note that we received a comment, which is discussed later in this document, expressing concern with the level of influence afforded to the reuse manufacturers under the process of adopting the AAMI guidelines.

We are in the process of preparing a proposed rule that would totally revise the conditions of coverage for ESRD facilities. We will solicit comment from the public on the merits of this proposal at that time. Until we have had an opportunity to hear from the facilities that would be impacted by this suggestion, we believe it is most appropriate to continue to pursue the rulemaking under the Administrative Procedure Act and provide an opportunity for participation by the affected entities.

### *B. Water Quality*

*Comment:* Two commenters recommended that we also incorporate the AAMI provisions relating to sampling and testing methodologies contained in sections 4.2.1 and 4.2.2 of "Hemodialysis Systems." They noted that the sampling and testing protocols are essential to obtaining results that are meaningful and lead to the desired outcome of good patient health and safety. They presented examples of factors that can erroneously influence test results, such as leaving samples at room temperature, sampling only at one site, and shortened incubation periods.

*Response:* We note the commenters' concern and fully endorse the provisions contained in sections 4.2.1 and 4.2.2. of the AAMI "Hemodialysis Systems" document. However, we note that the subject provisions are exceedingly detailed and include not only point of water collection within the dialysis system, but also time of assay, storage temperatures, filter technique, and culture media. While we encourage facilities to utilize these guidelines, we

believe that they are overly prescriptive. Moreover, the subject provisions are procedure-oriented as opposed to outcome-oriented and not necessary for ensuring Medicare beneficiary health and safety. We believe that we can meet the statutory mandate for beneficiary health and safety while permitting facilities some flexibility in sampling and testing procedures.

In addition, the adopted provisions of AAMI water quality standard address specific bacteriological and chemical purity levels. We also adopted the AAMI Appendix guidelines with regard to monitoring frequency. The guidelines address monitoring practices similar to sections 4.2.1 and 4.2.2 but in a more general, less prescriptive nature. We feel confident that these provisions provide enough detail to permit surveyors to adequately determine appropriate water quality. Moreover, these new standards represent a significant improvement over the assurances contained in the existing regulation. We believe that it would be unnecessarily burdensome and prescriptive to specify minute details as to the sampling techniques. Further, such specificity would be inconsistent with the Administration's commitment to reduce Federal regulatory burden. Consequently, we are not adopting the commenters' suggestion at this time.

We are, however, currently developing a complete revision of the ESRD conditions of coverage. One of the principal goals of this project is to make the conditions patient-centered and outcome-oriented. Ultimately, we may choose an outcome-oriented set of conditions regulating sampling methodology more explicitly. We will consider these comments as we develop the new conditions.

*Comment:* One commenter recommended that we apply the water quality standards to water used for reprocessing as well as for dialysate, noting that contaminated water can adversely affect reprocessing through the water rinse phases.

*Response:* The AAMI water standards that we have adopted were prepared, in collaboration with the industry, exclusively for water used during hemodialysis. The guidelines were not intended for adoption to the reuse process. We have incorporated water standards specifically for the reuse process from the AAMI reuse standards. The reuse standards contain water requirements in sections 7.1.2. and 11.4.1. We believe these standards are adequate to meet our need to ensure beneficiary health and safety.

### C. Hemodialyzer Reuse

*Comment:* One commenter took issue with the statement in the preamble of the proposed rule stating that, "Although the potential exists for adverse patient outcomes from reuse, reprocessing and reuse of dialyzers are safe when done properly." This commenter referenced the recent research indicating an association between increased mortality and reuse with certain germicides. The commenter concluded that it may be premature to state unequivocally that reprocessing and reuse of dialyzers are safe.

*Response:* We note that the sentence addressed by the commenter clearly includes the caveat that reprocessing is safe when done "properly". We do not believe the statement is misleading or erroneous in light of research findings.

Although the referenced research finds an association between increased mortality and reuse of certain germicides, it does not conclude that reuse is not safe. In addition, the Food and Drug Administration (FDA) has approved the product and its labelling, reviewed manufacturers' studies, and followed routine procedures that include product testing. Thus, we can conclude that the germicides currently marketed for reprocessing dialyzers do, in fact, work effectively to destroy bacteria.

HCFA and the FDA believe the research in question supports a conclusion that proper technique is essential for effective use of the germicides. Consequently, the FDA has been working with one manufacturer to strengthen product user education. In this regard, the manufacturer in question has taken several voluntary actions to promote proper use of the product, including issuing revised detailed instructions. In addition, the manufacturer has held numerous training sessions all over the nation to educate its customers regarding proper use of the product. Further, the manufacturer in question requires its customers to sign commitments to verify that they understand and will comply with product user instructions before further merchandise will be distributed.

*Comment:* Two commenters requested clarification of the requirement in § 405.2150(a)(2) that states that facilities may use only one germicide in reprocessing. Specifically, the commenters were concerned about the use of bleach and another germicide during reprocessing. One commenter specifically asked if it was necessary to discard all dialyzers currently being reused if the facility changes germicides.

*Response:* For purposes of reuse, bleach is considered a cleansing agent, not a germicide. Thus, many facilities use bleach as part of the reuse process to flush and clean blood deposits before the actual germicide soaking process is initiated. We do not intend to imply that this bleach cleansing process adversely affects the reprocessing. Since we do not consider bleach to be a germicide, the requirement to discard dialyzers treated with a different germicide does not apply to bleaching.

We do intend that a facility that changes germicides discard all those dialyzers reprocessed with the old germicide. We are concerned that exposing dialyzers to different germicides may cause membrane leaks. While we recognize that it may be expensive and considered wasteful by some facilities to discard dialyzers with test values that indicate they are still effective, we believe that this precaution is a necessary safety measure. Facilities should take this added expense into consideration when analyzing their alternatives and making a determination regarding the changing of germicides.

*Comment:* One commenter indicated that the prohibition against reuse of dialyzers for hepatitis B-positive patients that is contained in the AAMI guidelines is unjustified and costly to dialysis facilities. The commenter cited a report from the Centers for Disease Control that concluded that reuse of dialyzers was not associated with increased transmission of hepatitis B. Commenters supported measures other than a total ban against reuse for hepatitis B-positive patients, such as holding dedicated equipment in isolation areas, to eliminate the risk of cross-contamination of dialyzers.

*Response:* Hepatitis B is a highly contagious disease that has the potential to be extremely damaging to an ESRD patient. Given the highly contagious nature of the disease, the CDC has for many years strongly recommended extreme precaution and isolation of those patients who are hepatitis B-positive. Many physicians, nurses, and other professionals involved in the ESRD field have similarly supported the position of extreme caution in treating the hepatitis B-positive patient.

We want to point out that the AAMI provision related to banning reuse for hepatitis B-positive patients was developed in a public forum and reflects the views of many noted professionals. These guidelines were developed by a committee of national experts in a variety of ESRD-related fields. The committee's recommendations were then distributed to the AAMI membership at large for comment. Thus,

the prohibition against reuse of dialyzers for hepatitis B positive patients was developed by the medical community and reflects the general concern of most professionals that extreme caution is necessary in treating patients with the disease.

While there may be no appreciable evidence to demonstrate that reuse would increase the spread of hepatitis B, there is no conclusive evidence that reuse in this population is safe. Given that hepatitis B is very contagious and that the industry generally supports the prohibition, we believe that permitting reuse for hepatitis B-positive patients would be an inappropriate risk to the health and safety of ESRD patients.

*Comment:* One commenter expressed concern that the AAMI reuse guidelines provide too much latitude to device manufacturers in establishing operating parameters for their equipment. The commenter was concerned that ESRD facilities are a captive audience to manufacturers, who could design expensive equipment or procedures. Under the reuse regulations, which require compliance with the manufacturer's guidelines, facilities may be forced to bear financial burdens with little recourse. The commenter suggested that HCFA develop a process to allow ESRD facilities to appeal the application of excessively restrictive guidelines for equipment.

*Response:* We do not support the commenter's recommendation for HCFA to develop an appeal process for application of equipment guidelines. It is not within the purview of the HCFA to become involved in manufacturers' guidelines. The FDA, not HCFA, is responsible for approval of devices, equipment, and labelling, including manufacturers' instructions.

Manufacturers' product guidelines are very technical and are developed only after considerable research and deliberation with respect to complex technical and scientific matters. HCFA does not have the appropriate staffing or expertise to adjudicate facilities' appeals of these scientific matters. However, the FDA does offer recourse to facilities through its Office of Compliance. Facilities may contact the FDA by writing to: Food and Drug Administration, Office of Compliance, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20850.

In addition, we note that the manufacture of reprocessing devices, germicides, and equipment takes place in the competitive market arena. ESRD facilities are free to choose among a number of alternative strategies for reprocessing dialyzers, or they may choose not to reuse at all. Thus, we do

not believe that the facilities are a captive audience to the manufacturers given that there are a variety of dialyzer processing methods and reprocessing product manufacturers.

#### *D. Impact on the Hemodialysis Community*

We specifically solicited input from the commenters on our assumption that the adoption of the AAMI water and reuse standards would not represent a burden on the provider community as most are voluntarily complying with the AAMI guidelines.

*Comment:* Several commenters agreed with our conclusion that there would be little impact on facilities because most facilities already voluntarily comply with AAMI guidelines. Nonetheless, they voiced support for making the guidelines mandatory to force those few non-compliant facilities into appropriate practices.

*Response:* We appreciate the support for our proposal and are proceeding to publish the final regulations.

*Comment:* One commenter challenged our statement that the AAMI water standards are supported by scientific literature. The commenter also disagreed with the statement that the standards are based on industry consensus, since Government representatives participated in the AAMI guideline development.

*Response:* As noted earlier, the AAMI guidelines were developed by a committee of noted experts in hemodialysis. Once the committee formulated a draft document, it was circulated to AAMI membership for comment. The AAMI membership includes representatives of manufacturers, physicians, patients, technicians, and other fields. The committee seriously considered the comments and made appropriate revisions in the guidelines. Decisions reflected the majority of the committee members; no single member had authority to direct the decision or overrule the majority. While it is true that Government employees participated in the development of the guidelines, we do not believe that the fact that a Government representative participated in the process is an indication that the resulting guidelines are not representative of the industry consensus.

The AAMI committee utilized empirical data regarding microbial limits and epidemiological findings (among other things) in developing the guidelines. We acknowledge that by using the term "scientific literature" we may have inadvertently implied that the AAMI had performed clinical trials and

controlled experimentation. The intent of the statement was to indicate that the water quality limits established in the guidelines reflected reasonable assumptions and available empirical data.

#### **IV. Provisions of the Final Regulations**

We are adopting the provisions of the February 14, 1994, proposed regulations as final regulations without change.

#### **V. Collection of Information Requirements**

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.).

#### **VI. Regulatory Impact Statement**

##### *A. Introduction*

We generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612) unless the Secretary certifies that a final rule will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, all ESRD facilities are considered to be small entities.

Also, section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis if a final rule will have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

##### *B. Water Quality Standards*

This final rule incorporates industry standards on the quality of water used in dialysis into existing regulations thereby, enabling surveyors to accurately assess a facility's compliance with the standards on water quality. The AAMI standards are the results of a collaborative effort by health professionals and industry representatives to respond to clinical needs and to help ensure patient health and safety. The AAMI's recommended maximum levels for water contaminants have been clearly defined, reflect reasonable assumptions and available empirical data, and were developed through industry consensus. Under the AAMI water standard, the supplier/manufacturer of dialysis water treatment

equipment is responsible for ensuring that the water produced by the system routinely does not exceed the maximum allowable chemical contaminant levels. Because AAMI's acceptable contamination levels have been in effect since 1982 and are recognized as medically acceptable standards, we believe that manufacturers have been producing and facilities have been purchasing equipment capable of meeting these requirements. We understand that technology is in place for all facilities to meet the AAMI water standard. The public comments that we received on the proposed rule support this conclusion. Changes in water quality will be handled through consultation with State and local water authorities. Safe purity levels will be ensured through continued monitoring by the physician in charge of dialysis. Although contaminants in water used in dialysate may cause adverse patient reactions, actual documented adverse incidents are rare when the water is monitored properly. Because the AAMI water quality standard represents long-standing acceptable medical practice, we believe the vast majority of facilities already comply with this standard. Incorporation of the AAMI standard into the regulations will help ensure patient health and safety by providing surveyors with a measurable standard with which they may assess facility compliance, especially in the few facilities that do not voluntarily conform to the water quality guidelines adopted by the industry.

#### C. Reuse of Hemodialyzers

The AAMI "Reuse of Hemodialyzers" does not promote either single use or reuse of dialyzers. The guidelines were developed to acknowledge the widespread practice of reprocessing and provide recommendations for optimal hemodialyzer reprocessing. In January 1993, HCFA's Health Standards and Quality Bureau canvassed the 2,345 Medicare-certified ESRD facilities to determine if they practiced reuse, and, if so, the disinfecting protocols used. Sixty-five percent (1,532) of the facilities reported practicing reuse. Of these facilities, approximately 51 percent use renalin as the germicide; two-thirds of these facilities use an automated disinfecting system. Approximately 40 percent of the facilities reported using formalin/formaldehyde as the germicide, with manual and automated systems receiving equal use. Approximately 9 percent of the facilities practicing reuse reported using glutaraldehyde as the germicide, with the majority of these facilities using an automated

disinfecting system. Less than 1 percent of the facilities use other disinfecting methods.

Because the 1993 AAMI guidelines do not differ significantly from the 1986 guidelines (which all Medicare participating facilities practicing reuse already must meet) we believe that the great majority of the facilities practicing reuse will be in compliance with the new standards in this final regulation. The 1993 AAMI standards were developed through a public forum and their adoption was well publicized. They reflect the most up-to-date reuse procedures already practiced by many of the facilities. Moreover, we do not believe that incorporating the 1993 guidelines into our regulations, in and of itself, will prompt any facility to begin or discontinue reuse.

We expect that each facility will respond to these new standards based on the relationship of these standards to its current reuse practices and to factors such as whether or not the facility can buy new filters in quantity less expensively than it can upgrade its reuse practices. As we indicated earlier, 65 percent of the facilities are already reusing dialyzers. The major effect of this final rule will be to ensure that Medicare standards for reuse reflect safe and effective practices.

#### D. Conclusion

Because we are unable to predict the decisions facilities will make in response to this regulation, we are unable to quantify the potential effect it will have. All five public responses to the February 1994 proposed rule were favorable.

Beneficiaries may be reassured that HCFA has adopted specific water quality standards and updated its standards for reuse of hemodialyzers to ensure their health and safety. However, we expect that there will be a negligible effect on most beneficiaries and facilities since we believe these revisions will make no major changes in current facility operation or patient experience. This final rule is not expected to result directly in any increases or reductions in Medicare program expenditures.

For these reasons, we have determined, and the Secretary certifies, that this final rule will not have a significant economic impact on a substantial number of small entities and will not have a significant economic impact on the operations of a substantial number of small rural hospitals. Therefore, we are not preparing analyses for either the RFA or section 1102(b) of the Act.

In accordance with the provisions of Executive Order 12866, this final rule was not reviewed by the Office of Management and Budget.

#### List of Subjects in 42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Incorporation by reference, Kidney diseases, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Chapter IV, Part 405, Subpart U is amended as set forth below:

#### PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

##### Subpart U—Conditions for Coverage of Suppliers of End-Stage Renal Disease (ESRD) Services

A. The authority citation for part 405, Subpart U continues to read as follows:

**Authority:** Secs. 1102, 1861, 1862(a), 1871, 1874, and 1881 of the Social Security Act (42 U.S.C. 1302, 1395x, 1395y(a), 1395hh, 1395kk, and 1395rr), and sec. 353 of the Public Health Service Act (42 U.S.C. 263a), unless otherwise noted.

B. In § 405.2140, the heading of paragraph (a) is republished, and paragraph (a)(5) is revised to read as follows:

#### § 405.2140 Condition: Physical environment.

\* \* \* \* \*

(a) *Standard: building and equipment.* \* \* \*

(5)(i) The ESRD facility must employ the water quality requirements listed in paragraph (a)(5)(ii) of this section developed by the Association for the Advancement of Medical Instrumentation (AAMI) and published in "Hemodialysis Systems," second edition, which is incorporated by reference.

(ii) Required water quality requirements are those listed in sections 3.2.1, Water Bacteriology; 3.2.2, Maximum Level of Chemical Contaminants; and in Appendix B: Guideline for Monitoring Purity of Water Used for Hemodialysis as B1 through B5.

(iii) Incorporation by reference of the AAMI's "Hemodialysis Systems," second edition, 1992, was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51.<sup>1</sup> If any changes in

<sup>1</sup> The publication entitled "Hemodialysis Systems," second edition, 1992, is available for inspection at the HCFA Information Resource Center, 7500 Security Boulevard, Baltimore, MD

"Hemodialysis Systems," second edition, are also to be incorporated by reference, a notice to that effect will be published in the **Federal Register**.

\* \* \* \* \*

C. In § 405.2150, the undesignated introductory text and paragraph (a) are revised, paragraph (b) is removed, paragraphs (c) and (d) are redesignated as paragraphs (b) and (c), respectively, and redesignated paragraph (c)(1) is revised to read as follows:

**§ 405.2150 Condition: Reuse of hemodialyzers and other dialysis supplies.**

An ESRD facility that reuses hemodialyzers and other dialysis supplies meets the requirements of this section. Failure to meet any of paragraphs (a) through (c) of this section constitutes grounds for denial of payment for the dialysis treatment affected and termination from participation in the Medicare program.

(a) *Standard: Hemodialyzers.* If the ESRD facility reuses hemodialyzers, it conforms to the following:

(1) *Reuse guidelines.* Voluntary guidelines adopted by the AAMI ("Reuse of Hemodialyzers," second edition). Incorporation by reference of the AAMI's "Reuse of Hemodialyzers," second edition, 1993, was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51.<sup>2</sup> If any changes in "Reuse of Hemodialyzers," second edition, are also to be incorporated by reference, a notice to that effect will be published in the **Federal Register**.

(2) *Procedure for chemical germicides.* To prevent any risk of dialyzer membrane leaks due to the combined action of different chemical germicides, dialyzers are exposed to only one chemical germicide during the reprocessing procedure. If a dialyzer is exposed to a second germicide, the dialyzer must be discarded.

(3) *Surveillance of patient reactions.* In order to detect bacteremia and to maintain patient safety when unexplained events occur, the facility—

(i) Takes appropriate blood cultures at the time of a febrile response in a patient; and

(ii) If pyrogenic reactions, bacteremia, or unexplained reactions associated with ineffective reprocessing are identified, terminates reuse of hemodialyzers in that setting and does not continue reuse until the entire reprocessing system has been evaluated.

(b) \* \* \*

(c) \* \* \*

(1) Limit the reuse of bloodlines to the same patient;

\* \* \* \* \*

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 30, 1995.

**Bruce C. Vladeck,**

*Administrator, Health Care Financing Administration.*

[FR Doc. 95-22859 Filed 9-15-95; 8:45 am]

BILLING CODE 4120-01-P

## DEPARTMENT OF TRANSPORTATION

### Coast Guard

**46 CFR Parts 25, 28, 30, 31, 35, 37, 40, 50, 54, 55, 56, 57, 61, 67, 70, 71, 72, 76, 78, 79, 90, 91, 95, 97, 99, 106, 150, 154, 171, 174, 188, and 189**

[CGD 95-012]

RIN 2115-AF03

### Inspected and Uninspected Commercial Vessels; Removal of Obsolete and Unnecessary Regulations

**AGENCY:** Coast Guard, DOT.

**ACTION:** Final rule.

**SUMMARY:** The Coast Guard is modifying its regulations for both inspected and uninspected commercial vessels by removing and revising obsolete and unnecessary provisions. The Coast Guard expects that this final rule will reduce the administrative burden to government and industry, reduce government printing costs, and provide a more concise and useful Title 46, Code of Federal Regulations.

**DATES:** This rule is effective on October 18, 1995.

**ADDRESSES:** Unless otherwise indicated, documents referred to in this preamble are available for inspection or copying at the office of the Executive Secretary, Marine Safety Council (G-LRA/3406), U.S. Coast Guard Headquarters, 2100 Second Street SW., Washington, DC 20593-0001 between 8 a.m. and 3 p.m.,

Monday through Friday, except Federal holidays. The telephone number is (202) 267-1477.

**FOR FURTHER INFORMATION CONTACT:** LCDR R. K. Butturini, Design and Engineering Standards Division, Office of Marine Safety, Security, and Environmental Protection, (202) 267-2206.

### SUPPLEMENTARY INFORMATION:

#### Drafting Information

The principal persons involved in drafting this final rule are LCDR R. K. Butturini, Project Manager, Ms. Shereen Bell, Project Assistant and LT Rachel Goldberg, Project Counsel, Office of Chief Counsel.

#### Regulatory History

On May 9, 1995, the Coast Guard published a notice of proposed rulemaking (NPRM) entitled "Removal of Obsolete and Unnecessary Regulations" (60 FR 24748). The Coast Guard received one letter commenting on the NPRM. No public meeting was requested, and none was held specifically for this project. A public meeting was held on April 20, 1995 (60 FR 16423) to discuss the Coast Guard's regulatory process and regulatory reform. Relevant comments made at that meeting have been considered in this final rule.

#### Background and Purpose

On March 4, 1995, the President issued a memorandum calling on executive agencies to review regulations with the goals of—

- (1) Cutting obsolete regulations;
- (2) Focusing on results instead of process and punishment;
- (3) Convening meetings with the regulated community; and,
- (4) Expanding efforts to promote consensual rulemaking.

At an April 20, 1995 public meeting announced in the March 30, 1995 **Federal Register** (60 FR 16423) and in another notice published in the May 31, 1995 **Federal Register** (60 FR 28376), the Coast Guard declared its commitment to eliminating Coast Guard induced differences between the requirements that apply to U.S. vessels in international trade and those requirements that apply to similar vessels in international trade that fly the flag of responsible foreign nations. The purpose of this final rule is to begin the process of achieving this goal by removing or revising regulations that the Coast Guard has found to be obsolete and unnecessary.

In compiling the list of CFR sections included in this final rule, the Coast

21244-1850 and the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC. Copies may be purchased from the Association for the Advancement of Medical Instrumentation, 3300 Washington Boulevard, Suite 400, Arlington, VA 22201-4598.

<sup>2</sup>The publication entitled "Reuse of Hemodialyzers," second edition, 1993, is available for inspection at the HCFA Information Resources Center, 7500 Security Boulevard, Baltimore, MD 21244-1850 and the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC. Copies may be purchased from the Association for the Advancement of Medical Instrumentation, 3300 Washington Boulevard, Suite 400, Arlington, VA 22201-4598.